

Application Number 10/825,964
Amendment dated February 20, 2007
Responsive to Office Action mailed November 17, 2006

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REMARKS

This Amendment is responsive to the Office Action dated November 17, 2006. Applicant has amended claims 25, 53-57, and 60, and added claims 69-71. Claims 19-33, 35-45, 53-62, and 69-71 are pending.

Claim Objections

In the Office Action, the Examiner objected to claim 60, line 2, and suggested including the character --- (period) following the recitation of the limitation "coupled to the sensor via a lead" to designate the end of the claim. Applicant has amended claim 60 to include this character, as suggested by the Examiner. Applicant respectfully requests withdrawal of the objection.

Claim 25 has also been amended to correct a minor typographical error, i.e., for reasons unrelated to patentability.

Claim Rejection Under 35 U.S.C. § 102

In the Office Action, claims 19-26, 28, 29, 32, 33, 38-45, 53-58 and 62 were rejected under 35 U.S.C. § 102(e) as being anticipated by Poezevera (US 6,890,306). Claims 19-21, 23-31, 35-37 and 59-61 were also rejected under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111040). Applicant respectfully traverses the rejection. Both Poezevera and Ni et al. fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Independent Claims 19, 39, and 53

For example, both Poezevera and Ni et al. fail to teach or suggest an implantable medical device or an implantable means that determines a value of a sleep metric that indicates a probability of the patient being asleep based on a plurality of monitored physiological parameters, as required by Applicant's independent claims 19 and 39, respectively. Poezevera and Ni et al. also fail to teach or suggest an implantable medical device that determines a probability of a patient being asleep based on a physiological parameter, where the physiological

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parameter is one of blood pressure, muscular activity, arterial blood flow or galvanic skin response, as recited by Applicant's independent claim 53 as amended.

Claims 19 and 39 recite a sleep metric. Neither Poezevera nor Ni et al. teach or even suggest the notion of using a sleep metric that indicates a probability of the patient being asleep. Both Poezevera and Ni et al. teach devices that make a potentially inaccurate binary determination of whether a patient is awake or asleep based on the comparison of a sensed physiological parameter, rather than a sleep metric, to a threshold value. See, e.g., Poezevera, col. 4, ll. 56-64 and Ni et al., paragraph 53. In particular, Poezevera teaches a device that makes the binary determination based on individual comparison of two physiological parameters, minute ventilation and an acceleration sensor signal, to respective thresholds. Poezevera, col. 4, ll. 56-64. If the two parameters do not indicate the same state, i.e., sleep or awake, the trend of the minute ventilation signal is further analyzed to make the binary determination. Poezevera, col. 4, ll. 56-64. Similarly, Ni et al. teaches a device that determines whether a patient is asleep by comparing a sleep detection signal from a sensor to a sleep threshold or index. Ni et al. at paragraph 57. Ni et al. explicitly states that, "so long as the first sleep-related signal exceeds the sleep threshold 560, the patient is determined to be awake," thus indicating the direct use of a physiological parameter, rather than a sleep metric. Ni et al. at paragraph 91. In contrast to the teachings of Poezevera and Ni et al., claim 19, for example, requires a determination of a value of a sleep quality metric that indicates a probability of the patient being asleep based on a physiological parameter.

Applicant's disclosure makes clear that a sensed physiological parameter differs from a sleep metric. For example, a function or look-up table may be applied to a current physiological parameter value, mean or median of a physiological parameter, and/or variability of a physiological parameter to determine the sleep metric value. Applicant's disclosure at paragraph 56. A sleep metric value may be, for example, a numeric value that indicates a probability that a patient is asleep. Applicant's disclosure at paragraph 36. Poezevera and Ni et al., on the other hand, directly compare a value of a physiological parameter to a threshold value to make a sleep determination, rather than further processing the physiological parameter value to arrive at a sleep metric that indicates a probability that a patient is asleep.

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While Ni et al. teaches deriving parameters from sensed physiological parameters (*see, e.g.,* paragraph 51), the derived parameters do not indicate a probability of a patient being asleep, but rather “the signals and/or derived parameters associated with disordered breathing may be used to detect sleep disordered breathing.” Ni et al. at paragraph 88. A derived parameter that indicates sleep disordered breathing is not the same as a sleep metric that indicates a probability that a patient is asleep.

In fact, neither Poezevera nor Ni et al. determine a probability of a patient being asleep, as recited by Applicant’s independent claims 19, 39, and 53. Both references teach devices that determine whether the patient is either awake or asleep (*i.e.,* a binary determination), rather than determining a probability of sleep. As described in Applicant’s specification at paragraph [0020]:

Use of sleep metrics that indicate a probability of the patient being asleep for each of a plurality of physiological parameters may further increase the reliability with which an implantable medical device may determine whether a patient is asleep. In particular, rather than a binary sleep or awake determination for each of a plurality of parameters, sleep metric values for each of a plurality of parameters may be combined to yield an overall sleep metric value that may be compared to a threshold to determine whether the patient is asleep. In other words, failure of any one physiological parameter to accurately indicate whether a patient is sleeping may be less likely to prevent the implantable medical device from accurately indicating whether the patient is sleeping when considered in combination with other physiological parameters.

Nothing in the cited references mentions determining a probability of sleep, much less recognizes any benefits of determining a probability of sleep. Consequently, a skilled person would not have considered the features of independent claims 19, 39, or 53 obvious based on the teachings of the applied references.

Poezevera and Ni et al. fail to teach each and every element of Applicant’s claims 19, 39, and 53. Accordingly, Poezevera and Ni et al. fail to anticipate independent claims 19, 39, and 53 and the rejection to claims 19, 39, and 53 should be withdrawn.

Dependent Claims

The claims dependent on independent claims 19, 39, and 53, namely claims 20–26, 28, 29, 32, 33, 38, 40–45, and 54–58, incorporate all of the limitations of the respective base claims,

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and therefore are patentable for at least the reasons expressed above. Moreover, the dependent claims recite a number of additional features that are likewise not present in the cited references. Applicant addresses some of the features below for purposes of illustration.

Poezevera and Ni et al. fail to teach an implantable medical device that includes a processor that determines a value of an overall sleep metric based on the values of a plurality of sleep metrics, where each of the plurality of sleep metrics is based on a respective one of a plurality of physiological parameters, as recited by Applicant's claims 25 and 56 or a means for doing the same, as recited by Applicant's claim 42. Applicant's claims 26 and 27 recite a processor that determines a value of an overall sleep metric by averaging the values of the plurality of sleep metrics or by applying a weighting factor to at least one of the values of the plurality of sleep metrics, respectively.

As Applicant's disclosure recognizes, using an overall sleep metric value may help increase the reliability of the sleep determination, because failure of any one physiological parameter to accurately indicate whether a patient is sleeping may be less likely to prevent an accurate determination of whether a patient is asleep. Applicant's disclosure at paragraph 20. Poezevera and Ni et al. do not teach the use of a sleep metric, but rather rely on individual comparison of one or more physiological parameters to their respective threshold values to make a binary determination. Even if the physiological parameters were considered to be sleep metrics, which Applicant strongly disagrees with, Poezevera and Ni et al. do not contemplate determining an overall sleep metric value that is based on a plurality physiological parameters. Accordingly, the devices taught by Poezevera and Ni et al. do not use an "overall sleep metric," and the cited references fail to anticipate Applicant's claims 25, 42, and 56.

As another example of the deficiencies of the cited references, the cited references fail to teach a processor that determines whether a patient is in one of a of a rapid eye movement (REM) sleep state or a nonrapid eye movement (NREM) sleep state, as recited by Applicant's dependent claim 30. The Office Action asserted that Ni et al. teach each and every element of claim 30. While Ni et al. teaches a disordered breathing detection device that senses eye movement (paragraph 52), Ni et al. fails to teach a device that differentiates between different eye movement states. Accordingly, Ni et al. does not teach a disordered breathing detection device that determines whether the patient is in one of a REM sleep state or a NREM sleep state.

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Claims 33, 45, and 58 recite storage of information indicating when the patient is asleep for retrieval by a user. Poezevera and Ni et al. make no mention of such a feature. The Office Action recognized that Ni et al. does not anticipate claims 33, 45, and 58, but found that Poezevera anticipated claims 33, 45, and 58. In particular, the Office Action characterized the memory of the device taught by Poezevera as disclosing a processor that stores information for retrieval by a user (claims 33 and 58) or a means for storing information for retrieval by a user (claim 45). However, the memory in Poezevera is used for storing software instructions, rather than information indicating when the patient is asleep. Poezevera, col. 6, ll. 18-52. Poezevera makes no mention of even the desirability of storing information indicating when the patient is asleep for retrieval by a user, let alone include a description of such a feature.

Both Poezevera and Ni et al. fail to disclose each and every limitation set forth in claims 19-33, 35-45, and 53-62. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 19-33, 35-45, 53-62 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

New Claims:

Applicant has added claims 69-71 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. For example, the references fail to disclose an implantable medical device that determines a value of a sleep metric that indicates a probability of a patient being asleep based on the physiological parameters, where the value of the sleep metric comprises a number within a range of about 0 to about 1, as recited by claim 69. No new matter has been added by the new claims.

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CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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By:

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